

## CONTESTED SCIENCE AND EXPOSED WORKERS: ASARCO AND THE OCCUPATIONAL STANDARD FOR INORGANIC ARSENIC

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In recent years, public health researchers and historians have critically examined industry-sponsored research and its role in influencing scientific knowledge, discourse, and regulatory decision making.<sup>1-3</sup> This article examines occupational health research on arsenic conducted by the American Smelting and Refining Company (ASARCO) and its relationship to the decision-making process for the arsenic standard set by the Occupational Safety and Health Administration (OSHA).

ASARCO owned and operated a copper smelter near Tacoma, Washington, that was the only producer of arsenic trioxide in the U.S. when the OSHA standard-setting process began in the mid-1970s. ASARCO, at that time, was “. . . the world's largest processor of non-ferrous metals.”<sup>4</sup> The Tacoma Smelter was at the center of federal efforts to regulate arsenic in the workplace as well as the environment.

### METHODS

This historiographic research draws on a variety of primary and secondary documents. Environmental Protection Agency (EPA), OSHA, and National Institute for Occupational Safety and Health (NIOSH) documents were obtained from federal archives. Internal ASARCO documents were obtained from court records. Other sources included media accounts and scientific journal articles. Documents were intensively reviewed and key elements were abstracted and organized in a timeline to facilitate chronological understanding of events. The narrative was constructed through a careful analysis of the documents, and two short interviews were used to obtain clarifying information not available in the documents.

### FINDINGS

#### A brief history of the science of occupational arsenic exposure

NIOSH estimated in 1975 that 1.5 million workers in the U.S. were exposed to inorganic arsenic in the

workplace.<sup>5</sup> Arsenic trioxide is one of the most toxic forms of inorganic arsenic and is produced largely as a byproduct of copper smelting.<sup>6</sup> The International Agency for Research on Cancer (IARC) classifies arsenic as Group 1, carcinogenic to humans,<sup>7</sup> and the National Toxicology Program lists arsenic as a known human carcinogen.<sup>8</sup> In the last 20 years, a large number of epidemiologic studies have linked inorganic arsenic exposure with cancers of the lung, skin, kidney, bladder, colon, uterus, prostate, stomach, and liver.<sup>9,10</sup> Non-cancer effects include diabetes mellitus,<sup>11</sup> cardiovascular disease,<sup>12</sup> skin diseases such as hyperpigmentation and keratoses, peripheral neuropathy, and adverse reproductive effects.<sup>13</sup>

In the early 1970s, the contemporary scientific literature on the health effects of occupational arsenic exposure was beginning to develop. Since the late 1800s, there had been speculation that arsenic might be a respiratory carcinogen.<sup>14</sup> Systematic study began in the 1940s with an examination of worker mortality at a sheep dip factory in England. Arsenic-exposed workers were found to have higher lung cancer mortality than other workers in the same town.<sup>15</sup> Vintners in the Moselle Valley of Germany who used arsenic on wine grapes were found at autopsy to have cancers of various organs including the lungs.<sup>16</sup> In 1957, miners in Rhodesia were reported to have higher than expected rates of lung cancer, hypothesized to be related to arsenic-bearing gold ore.<sup>17</sup>

In the U.S., researchers at the National Cancer Institute (NCI) began in-depth exploration of the relationship between arsenic and occupational lung cancer in the 1960s. A study of underground metal miners exposed to low levels of radiation found higher rates of respiratory cancer mortality than expected. Arsenic was a suspected etiologic agent. However, the finding was inconclusive because of multiple potential carcinogens in the mining environment.<sup>18</sup> In an attempt to find an occupational group with a relatively pure exposure to arsenic, NCI researchers turned to the study of smelter workers at the Anaconda Smelter in the Deer Lodge Valley of Montana.<sup>19</sup>

It was this study, published by Drs. Anna Lee and Joseph Fraumeni in 1969, that provided convincing evidence to many that occupational exposure to arsenic was a factor in the etiology of lung cancer. Arsenic-exposed workers had a threefold increased risk of respiratory cancer in comparison with male residents of the state. The most highly exposed workers exhibited

an eightfold increased risk.<sup>19</sup> Anaconda, like Tacoma, smelted high arsenic ore, and produced arsenic trioxide from 1910 until 1965.<sup>20</sup>

### **ASARCO's attempts to influence the science of occupational arsenic**

Prior to the publication of the Lee and Fraumeni study, an internal ASARCO document showed that company scientists intended to influence the conclusions of the study. Kenneth Nelson, ASARCO's Vice President for Environmental Affairs, and Dr. Sherman Pinto, ASARCO's Corporate Medical Director and Tacoma Smelter physician, received a copy of the paper while it was in draft form. In a confidential letter to ASARCO managers in New York, Nelson wrote:<sup>21</sup>

Among the little-known and perhaps unappreciated advantages that Dr. Pinto and I have is that we have numerous trusted friends in State and Federal health agencies. Through one of these friends I recently obtained an advance copy of a paper describing a study done of lung cancer incidence among smelter workers exposed to arsenic and sulfur dioxide. This paper ordinarily would have been published before we had a chance to see it. Two sentences from the author's abstract will give you an idea of the possible impact of the paper if published in its present form: "The excess of respiratory cancer was as high as eightfold among employees who worked more than 15 years and were heavily exposed to arsenic, and showed a gradient in proportion to the degree of exposure to arsenic and sulfur dioxide. The findings indicate that inhaled arsenic is a respiratory carcinogen in man and that this effect may be enhanced by sulfur dioxide."

There are holes in the paper and in the author's reasoning. From Dr. Pinto I have received two pages of sharp, hard criticisms which I shall convey to my friend who in turn will see that the criticism get to the author. I am having an expert statistician review the statistical methods employed and his criticisms will be passed along. As a result of these actions, we hope the author's conclusions and the paper will be tempered considerably or even shelved. We don't need any more trouble than we have with fears about asbestos, cadmium and lead.

It is not clear whether ASARCO's critiques reached the authors. Interviews with both authors revealed that neither was aware of ASARCO's intent to influence their research. The published version of the abstract placed more emphasis on sulfur dioxide or other unidentified chemicals as possible cofactors in lung cancer etiology, with the last sentence reading: "The findings support the hypothesis that inhaled arsenic is a respiratory carcinogen in man, but an influence of sulfur dioxide or unidentified chemicals,

varying concomitantly with arsenic exposure, cannot be discounted."<sup>19</sup>

How or why this change occurred is impossible to discern from the available evidence. That ASARCO intended to influence the findings of this study is not in doubt. That they believed their critiques could surreptitiously reach the authors is clear from Nelson's letter to Soutar. However, whether the critiques reached the authors as intended is unknown. Dr. Lee stated in an e-mail to this author: "While manuscripts go through many drafts during their preparation, in no way were any of the drafts changed as a result of pressure from outside NCI." (Personal communication, Dr. Anna Lee, formerly Associate Professor, Center for Health Policy and Research, Department of Medicine, University of California Irvine, 2007 Feb 22.) Dr. Fraumeni thought that the change in the abstract was most likely made by Dr. Lee and himself in an attempt to be conservative about the paper's assertions, as this was a first-time finding. (Personal communication, Dr. Joseph Fraumeni, Director, Division of Cancer Epidemiology and Genetics, National Cancer Institute, 2005 Sep 14.)

Even prior to the publication of the Lee and Fraumeni study, ASARCO had a long-standing interest and participation in scientific discussions of arsenic's carcinogenic properties.

### **Early smelter research supported by ASARCO**

Nearly 20 years before the Anaconda smelter study, Snegireff and Lombard of Harvard University published the first study of smelter workers in the U.S. and cancer risk.<sup>22</sup> They compared the cancer mortality experience of workers at two U.S. smelters. In one (Plant A), workers were exposed to large quantities of arsenic trioxide dust, and in the other (Plant Z) workers were unexposed. Though not mentioned in the paper, Plant A was the Tacoma Smelter, and the research was conducted for ASARCO. That this was an ASARCO study involving the Tacoma Smelter was discerned from a confidential internal memorandum.<sup>23</sup>

Snegireff and Lombard found proportionately more cancer deaths among smelter workers than among males in the smelter states. However, for both plants, the differences were not statistically significant. Lung cancer deaths were reported but not analyzed.<sup>22</sup> A reanalysis of these data 24 years later by NIOSH concluded that workers at Plant A (the Tacoma Smelter) "experienced a 460% excess in respiratory cancer deaths relative to mortality from all causes in 1938."<sup>25</sup> However, Snegireff and Lombard's conclusions were the following: "... the handling of arsenic trioxide in the industry studied does not produce a significant change in the cancer mortality of the plant employ-

ees; hence, other factors in addition to arsenic must be considered significant in the causal relationship to cancer.”<sup>22</sup>

### The Delaney Clause

In the late 1950s, ASARCO played a lead role in organizing U.S. arsenic producers to “present a united front”<sup>24</sup> in addressing concerns regarding the carcinogenicity of arsenic prompted by the Delaney Clause,<sup>25</sup> which prohibited known carcinogens as residue on food.

In a 1959 internal memo, an ASARCO manager related the plans developed at a meeting of arsenic industry representatives and asked ASARCO medical staff to assist by further studying Tacoma workers:<sup>23</sup>

Last week at the Arsenic Research Committee meeting, the industry expressed its great concern about this situation, and I have been requested to outline a preliminary approach to this problem on an industry-wide basis. Accordingly, I have requested each company to prepare a comprehensive medical survey and history of cancer incidence in their individual arsenic plants.

As you know, ASARCO has prepared such a survey of Tacoma covering the period 1924 to 1949. The data were published in the A.M.A. Archives of Industrial Hygiene and Occupational Medicine, Sept. 1951 by Dr. L.S. Snegireff. The title of this article is “Arsenic and Cancer, Observations in Metallurgical Industry.”

I strongly urge that ASARCO medical staff prepare another similar article for the period from 1949 to 1959 inclusive. I cannot over-emphasize the need or the urgency for these additional data.

This request resulted in a mortality study of Tacoma Smelter workers covering the time period 1949–1960. Published in 1963 by Dr. Pinto and his coauthor Bennett of the University of Washington, the study examined workers who were assigned to exposed or unexposed groups based on the area of the plant in which they had worked. They found approximately twice the expected number of deaths from lung cancer in both the exposed and unexposed groups. Due to the small number of deaths in the exposed group, no conclusions about this group could be made.<sup>26</sup>

Regardless, Pinto and Bennett wrote: “This comparison shows there were a few more deaths in the non-arsenic exposed respiratory cancer group than were to be expected by calculation, and further study of these cases is continuing. At present we can say arsenic trioxide was not one of the possible external factors associated with this problem.”<sup>26</sup> Finally, on the basis of their study, they claimed that industrial exposure to arsenic in the U.S. does not cause cancer:<sup>26</sup>

On the basis of our observation we can go a step further [than Doll] and say that arsenic trioxide absorption of

the range we have described in industry does not cause cancer. Arsenicism in modern United States industry is extremely rare, and this fact was noted many years ago by Alice Hamilton.

The reference to Doll’s work is to a review article on lung cancer published in 1959, in which Doll summarized the evidence on occupational arsenic exposure and lung cancer in the following way: “It seems probable, therefore, that exposure to inorganic arsenic in the air may produce lung cancer, if the amount present is sufficient to produce gross evidence of arsenicism. In the absence of such evidence, it seems most unlikely that the amount of arsenic inspired could be sufficient to account for any important industrial risk of the disease.”<sup>27</sup> A common view throughout the first half of the 20th century was that to attribute cancer to arsenic, clinical evidence of arsenic exposure, such as keratoses or hyperpigmentation, had to be present.<sup>28–30</sup>

In its review of the Pinto-Bennett study, NIOSH rejected the contention that any workers were unexposed because of known high exposures in the plant and elevated urinary arsenic levels in nearby community residents, indicating that exposure to arsenic even went beyond the smelter grounds.<sup>31</sup> Further, the average urinary arsenic level of the unexposed group was almost 10 times higher than had been reported in an earlier Public Health Service study aimed at determining urinary arsenic levels in a nonworker, unexposed population.<sup>32</sup> When exposed and unexposed workers were examined together, the study showed about a two-fold increase in the risk of dying from respiratory cancer.<sup>5</sup> These two ASARCO-supported studies of Tacoma Smelter workers were characterized by methodological and analytic flaws, with findings favorable to industry. Until the publication of the Lee and Fraumeni study, they were the only published studies of smelter workers, arsenic exposure, and cancer risk in the U.S.

### Developing an occupational standard

In 1974, NIOSH forwarded a Criteria Document to OSHA, which proposed a tenfold reduction in the existing occupational arsenic standard of 500  $\mu\text{g}/\text{m}^3$ , set in 1947 to prevent “incapacitating dermatitis in a few hours.”<sup>33</sup> Meeting the proposed 50  $\mu\text{g}/\text{m}^3$  standard at the Tacoma Smelter would have required significant effort on ASARCO’s part since, in 1974, most smelter departments had mean air arsenic concentrations higher than 50  $\mu\text{g}/\text{m}^3$ , with the mean in the arsenic plant well above the existing 500  $\mu\text{g}/\text{m}^3$  standard, at 2,264  $\mu\text{g}/\text{m}^3$ .<sup>34</sup>

Within six months, two chemical companies and one smelting company provided NIOSH with previously unpublished data on their arsenic-exposed workers.

Studies at all three companies found increased lung cancer mortality associated with arsenic exposure.<sup>35-37</sup>

ASARCO, however, maintained that their data did not show increased risk to Tacoma workers. Company officials testified to this at a September 1974 OSHA fact-finding hearing. Based on an update of the Pinto-Bennett study, they reported "... no increased mortality from arsenic exposure among workers ..."<sup>38</sup> and the company argued that there was no need to change the standard. ASARCO scientists suggested that increased lung cancer mortality found in the chemical company studies was due to exposure to other carcinogens in the workplace, not arsenic.<sup>38</sup>

However, NIOSH took issue with ASARCO's interpretation of their data. Though apparently not aware that the Snegireff-Lombard study concerned the Tacoma Smelter, their reanalysis of both prior ASARCO studies showed excess respiratory cancer mortality.<sup>5,39</sup> Had NIOSH known that the Snegireff and Lombard study concerned the Tacoma Smelter, a clear pattern of increased risk of respiratory cancer mortality within this copper smelter would have been evident between 1922 and 1971, the period of time covered by the studies of Snegireff-Lombard, Pinto-Bennett, and Milham-Strong.<sup>40</sup> The consistency of this finding over time, in this copper smelter, would have only lent more certainty to NIOSH's view that arsenic was a respiratory carcinogen and copper smelter workers were at risk.

Concurrent with NIOSH's scrutiny of ASARCO's scientific claims, the Washington State Department of Social and Health Services, as part of its investigation of arsenic exposure in residents living near the smelter, requested that ASARCO turn over its data on workers, beginning in 1972.<sup>41</sup> By 1976, Dr. John A. Beare, the Department's Director, was threatening the company with legal action to obtain the data.<sup>42</sup> While this conflict was ongoing, Dr. Milham, a state epidemiologist, tried another approach. He examined death certificates, coded by occupation, from the county in which the smelter was located. From death certificates, he identified former smelter workers and their causes of death and estimated that Tacoma Smelter workers had a statistically significant twofold risk of dying from lung cancer.<sup>40</sup> He found more deaths from respiratory cancer than had been reported in the Pinto-Bennett study, which he attributed to Dr. Pinto inappropriately coding to the immediate rather than underlying cause of death.<sup>43</sup>

In March 1975, the New York Academy of Medicine held a meeting on Occupational Carcinogenesis. Data were presented that further heightened concern about arsenic's carcinogenic properties. NIOSH scientists

reported that a worker exposed for 40 years at  $3 \mu\text{g}/\text{m}^3$  on an eight-hour time-weighted average basis would experience twice the expected risk of mortality from lung cancer.<sup>39</sup> Two other investigators presented data that suggested that exposure to smelter arsenic pollution could increase lung cancer rates in surrounding communities.<sup>44,45</sup> NIOSH's Acting Director, Edward J. Baier, stated in testimony that these new data influenced the Agency's decision to revise its proposed standard.<sup>46</sup> The new recommendation, published in the Federal Register in January 1975, was that no 15-minute breathing zone contain arsenic concentration higher than  $2 \mu\text{g}/\text{m}^3$ , the lowest detectable level, due to uncertainty regarding the level at which arsenic was carcinogenic.<sup>31</sup>

### **The OSHA standard and ASARCO's continuing research**

The standard that OSHA proposed in 1975 was  $4 \mu\text{g}/\text{m}^3$  with an action level of  $2 \mu\text{g}/\text{m}^3$ .<sup>31</sup> Hearings began in April 1975. A week prior to the hearings, Kenneth Nelson wrote a letter to OSHA and disclosed that Dr. Pinto and Dr. Enterline, a collaborator at the University of Pittsburgh, would be presenting data from a new study that showed an excess of lung cancer deaths among Tacoma Smelter workers.<sup>47</sup> The new study, referred to as the Pinto-Enterline study,<sup>48</sup> reported risk estimates similar to Lee and Fraumeni. Nelson, however, in oral testimony on the findings, characterized the role of arsenic in the study as uncertain: "Additional complexities such as the possible synergistic effects of cigarette smoking, possible influences of a socio-economic or ethnic-origin nature, possible effects of other air contaminants associated with arsenic, all lend uncertainties to identifying the cause or causes of elevated lung cancer death rates."<sup>49</sup>

### **Arguing about a model**

NIOSH argued that uncertainty regarding the level at which arsenic caused lung cancer required a lowest detectable standard. They viewed the relationship between exposure and lung cancer as linear, with no threshold. ASARCO, however, argued strongly that a threshold existed. The company based its argument on the lowest exposed group in the Pinto-Enterline study, which had a standardized mortality ratio of less than 100. However, this was true only for those workers exposed for fewer than 25 years. The lowest exposed group with exposure duration of more than 25 years exhibited a threefold increased risk of lung cancer mortality. Regardless, ASARCO argued that a  $100 \mu\text{g}/\text{m}^3$  standard would be protective of health.<sup>49</sup>

In support of the threshold argument, the Ana-



conda Company funded a reanalysis of the Anaconda worker data,<sup>50</sup> which tentatively concluded that workers exposed to less than 100  $\mu\text{g}/\text{m}^3$  of arsenic did not have a statistically significant increased risk of death from lung cancer. In the smelting industry's court challenge to the OSHA standard, they asked the court to privilege this paper over others. The court declined and deferred to OSHA's scientific expertise.<sup>51</sup>

### The relationship between worker exposure and community health concerns

Even among mining and smelting companies, ASARCO was notable for the vociferousness with which it opposed the occupational arsenic standard. The company cited a number of arguments such as cost, technological infeasibility, and what they considered uncertain science for their opposition. They threatened that OSHA's proposed 4  $\mu\text{g}/\text{m}^3$  standard could cause them to close the Tacoma Smelter.<sup>52,53</sup> This was a compelling argument to some in the local community and apparently to OSHA, which set the standard at 10  $\mu\text{g}/\text{m}^3$ , in deference to industry's concerns about cost.<sup>54</sup>

At the time, the Tacoma Smelter was also under scrutiny by the EPA and local environmental regulators for environmental releases of arsenic, lead, and sulfur dioxide. The level at which the workplace standard was set was significant to the outcome of other environmental regulations.

By the early 1970s, the Washington State Department of Social and Health Services had documented significant arsenic exposure in the community around the smelter, particularly in children. Urinary arsenic levels in some children living near the smelter were reported to be equivalent to levels in some smelter workers.<sup>55</sup> Arsenic in community air at times exceeded NIOSH's proposed 2  $\mu\text{g}/\text{m}^3$  standard, and OSHA's proposed 4  $\mu\text{g}/\text{m}^3$  standard. This fact was widely known among environmental regulators. A 1976 EPA report<sup>56</sup> found the highest air concentrations for arsenic in the U.S. less than one-half mile from the Tacoma Smelter, with a maximum quarterly average of 4.86  $\mu\text{g}/\text{m}^3$  in 1973. A 24-hour maximum concentration measured 15.7  $\mu\text{g}/\text{m}^3$ . If the OSHA standard were set at 2 or 4  $\mu\text{g}/\text{m}^3$ , community air would on occasion exceed the occupational standard.

Because the purpose of the occupational standard was to protect health, this elevated level would significantly undermine ASARCO's arguments to environmental regulators that community health was not being harmed by smelter emissions. Environmental exposure standards are generally more restrictive than worker standards to account for differential vulnerability of community members to environmental toxins, such as

children or pregnant women, as well as the potential for longer duration of exposure than workers would experience during a typical eight- to 10-hour shift.<sup>57</sup>

## CONCLUSION

The subsequent science of arsenic appears to have validated NIOSH's precautionary approach to the occupational standard. Over the next two decades, Dr. Enterline continued his study of Tacoma Smelter workers. In subsequent papers, he reworked exposure estimates and concluded that arsenic was much more potent at low levels than previously thought and that epidemiologic studies in high-exposure environments may have underestimated risk at low levels.<sup>58,59</sup>

While NIOSH, OSHA, and the courts did not accept ASARCO's challenges to the science, the smelting industry was successful in lengthening the standard-setting process. It was 1985 when the court upheld OSHA's 10  $\mu\text{g}/\text{m}^3$  standard. While litigation was ongoing, certain provisions of the standard were stayed,<sup>60</sup> and air concentrations of arsenic at the plant remained well above 10  $\mu\text{g}/\text{m}^3$ .<sup>61</sup> The final court decision was a moot point for Tacoma Smelter workers because ASARCO closed the smelter in 1985, citing in part the cost of environmental regulation.<sup>62</sup>

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